

Environmental Protection Agency

§ 152.92

on the date EPA approves the applicant's present application.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008; 79 FR 6825, Feb. 5, 2014]

§ 152.90 The selective method.

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has previously been submitted to the Agency. This section summarizes the procedures that an applicant must follow if he chooses the selective method of demonstrating compliance. Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or claiming a data gap.

(a) *List of data requirements.* (1) Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5) for the first time.

(2) The applicant must list the applicable requirements, as prescribed by part 158 of this chapter, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulators' exemption.

(b) *Methods of demonstrating compliance.* The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to §152.91.

(2) Submission of a new valid study. Refer to §152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with

any necessary written authorizations or offers to pay. Refer to §152.93.

(4) Citation of a public literature study. Refer to §152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to §152.95.

(6) Claim of data gap. Refer to §152.96.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007; 79 FR 6825, Feb. 5, 2014]

§ 152.91 Waiver of a data requirement.

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) *Request for an extension of an existing waiver.* An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for the product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Reregistration Eligibility Decision (RED) document or registration review decision document, and explain why that waiver should apply to the product.

(b) *Request for a new waiver.* An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45 or 40 CFR 161.45.

(c) *Effect of denial of waiver request.* A decision by the Agency to deny a written request for a new waiver or an extension of an existing waiver is a final Agency action. Following denial, the applicant must choose another method of satisfying the data requirement.

[49 FR 30903, Aug. 1, 1984, as amended at 72 FR 61028, Oct. 26, 2007; 79 FR 6825, Feb. 5, 2014]

§ 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the

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Agency should not be resubmitted but should be cited in accordance with § 152.93.

§ 152.93 Citation of a previously submitted valid study.

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) *Study originally submitted by the applicant.* If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) *Study previously submitted by another person.* If the applicant is not the original data submitter, the applicant may cite the study only in accordance with paragraphs (b) (1) through (3) of this section.

(1) *Citation with authorization of original data submitter.* The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

(i) Identification of the applicant to whom the authorization is granted;

(ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;

(iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and

(iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) *Citation with offer to pay compensation to the original data submitter.* The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(F)(i) without written authorization from the original data submitter if the applicant certifies to the Agency

that he has furnished to the original data submitter:

(i) A notification of the applicant's intent to apply for registration, including the proposed product name and a list of the product's active ingredients;

(ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study; and

(v) The applicant's name, address, and contact information, including a telephone number and email address.

(3) *Citation without authorization or offer to pay.* The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in § 152.83(c).

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008; 79 FR 6825, Feb. 5, 2014]

§ 152.94 Citation of a public literature study or study generated at government expense.

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

(1) A valid study from the public literature.

(2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(F).

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